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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,342	01/09/2004	Michael H. Jones	14875-068002	8636

26161 7590 03/24/2006

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EXAMINER	
WAX, ROBERT A	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/754,342	JONES, MICHAEL H.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-37 and 40-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *32-34,40-42,44-46 and 48* is/are allowed.

6)☒ Claim(s) *35-37,43,47 and 49-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06022005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 2, 2005 has been entered.

2. It is unclear why the instant application wasn't picked up for action sooner but the present examiner just received the case in March 2006. Any inconvenience is regretted.

Information Disclosure Statement

3. The information disclosure statement filed June 2, 2005 has been considered. Please see the attached initialed PTO-1449.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 11, line 11 and page 26, line 10. Applicant is required to delete or disable the embedded hyperlink and/or other form of

browser-executable code. Deletion of the http:// portion will disable the link. See MPEP § 608.01.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 49-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acid that encodes SEQ ID Nos.: 1 or 10, does not reasonably provide enablement for isolated nucleic acid that encodes SEQ ID Nos.: 1 or 10 with 1-50 conservative amino acid substitutions, resulting in nucleic acids that are less than 100% identical to SEQ ID Nos.: 2 or 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims read on nucleic acids that encode SEQ ID Nos.: 1 or 10 with 1-50 conservative amino acid substitutions. Thus, the claims read on any nucleic acid that encodes proteins similar to SEQ ID Nos.: 1 or 10 having the original function, some altered function or no function at all. The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the

claimed invention would require undue experimentation by an artisan of ordinary skill in the art.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is immense because the number of possible amino acid sequences to be encoded is at least many thousand. There could be any of 20 substitutions at any 50 positions times the number of "50 positions"; (2) the amount of guidance provided by the specification is none since there is no discussion of where in the protein the activity is localized and no information is

provided as to where one could make modifications and still maintain the function. Continuing, (3) the specification is totally devoid of any working examples; as for the next Wands factor, (4) the nature of the invention is DNA encoding a transcriptional regulatory factor comprising bromodomains. The prior art (5) shows other transcriptional factors that contain a bromodomain but not the specifically claimed sequences; (6) the relative level of skill in this art is very high; (7) the predictability of the art is low since *a priori* it is not possible to predict which changes will result in functional polypeptides. Finally, (8) the claims are quite broad because the number of possible mutants is very large and varied.

Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

7. Claims 49-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are directed to isolated nucleic acid that encodes SEQ ID Nos.: 1 or 10 and also to nucleic acid that encodes SEQ ID Nos.: 1 or 10 with 1-50 conservative amino acid substitutions, resulting in nucleic acids that are less than 100% identical to SEQ ID Nos.: 2 or 9. Thus the claimed sequences that are less than 100% identical to SEQ ID Nos.: 2 or 9 are defined only by the characteristic of a particular percent identity to the base sequence.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, Paragraph 1, "Written Description" Requirement, published at Federal Register, Vol. 66, No. 4, pp. 1099-1111 outline the method of analysis of claims to determine whether adequate written description is present. The first step is to determine what the claim as a whole covers, i.e., discussion of the full scope of the claim. Second, the application should be fully reviewed to understand how applicant provides support for the claimed invention including each element and/or step, i.e., compare the scope of the claim with the scope of the description. Third, determine whether the applicant was in possession of the claimed invention as a whole at the time of filing. This should include the following considerations: (1) actual reduction to practice, (2) disclosure of drawings or structural chemical formulas, (3) sufficient relevant identifying characteristics such as complete structure, partial structure, physical and/or chemical properties and functional characteristics when coupled with a known or disclosed correlation between function and structure, (4) method of making the claimed invention, (5) level of skill and knowledge in the art and (6) predictability of the art. For each claim drawn to a single embodiment or species, each of these factors is to be considered with regard to that embodiment or species. For each claim drawn to a genus, each of these factors is to be considered to determine whether there is disclosure of a representative number of species that would lead one skilled in the art to conclude that applicant was in possession of the claimed invention. Where skill and knowledge in the art is high adequate written description would require fewer species to be disclosed than in an art

where little is known; further, more species would need to be disclosed to provide adequate written description for a highly variable genus.

First, what do the claims as a whole cover? Claims 49-68 are directed to isolated nucleic acid that encodes SEQ ID Nos.: 1 or 10 and also to nucleic acid that encodes SEQ ID Nos.: 1 or 10 with 1-50 conservative amino acid substitutions, resulting in nucleic acids that are less than 100% identical to SEQ ID Nos.: 2 or 9.

Second, how does the scope of the claims compare to the scope of the disclosure? The disclosure contains the same language found in claims 49-68. Thus, the specification is of the same scope as the claims.

Third, the factors need to be considered.

(1) What was actually reduced to practice?

Clearly, the specific sequences shown were actually reduced to practice.

(2) Is there disclosure of drawings or structural chemical formulas?

The sequence is given for the specific nucleic acids that were reduced to practice. No sequences are provided that differ from those exact sequences. There is no disclosure of how any portion of the sequence gives rise to a polypeptide having the transcriptional regulatory function.

(3) Are there sufficient relevant identifying characteristics disclosed?

The only identifying characteristics shown are the percent of identity to the base sequence. There is no disclosed correlation between the function and the different sequences encoding the polypeptides that are less than 100% identical.

(4) Is there at least one method of making the claimed invention disclosed?

Yes.

(5) What is the level of skill in the art and what knowledge is present in the art?

The level of skill in the art of recombinant transcriptional regulators is high, about that of a PhD scientist with several years' experience with molecular biology.

The specification indicates that the bromodomain is a characteristic amino acid motif seen in transcriptional regulatory factors but the prior art does not teach either SEQ ID No.: 2 or 9.

(6) What is the level of predictability of the art?

The level of predictability in this art is very low since, until the mutation is actually made, there is no information upon which to base a prediction of what its function might be. The classic example of how a change in the sequence of a protein can make a profound impact on function is hemoglobin. There, a single amino acid difference determines if a person has sickle-cell anemia or not. Thus, the level of predictability is low.

Thus, having analyzed the claims with regard to the Written Description guidelines, it is clear that the specification does not disclose a representative number of species which would lead one skilled in the art to conclude that applicant was in possession of the claimed invention.

8. Claims 35-37, 43 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 35 recites 50°C as high stringency conditions for hybridization where the specification, at page 10, line 12, clearly defines 50°C as moderate stringency. The concept that 50°C constitutes high stringency is not taught in the specification.

Claim Rejections - 35 USC § 112, Second Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 35-37, 43 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are incomplete since there is no temperature defined for the wash step, which, as applicants are aware, is the critical step for determining the level of stringency.

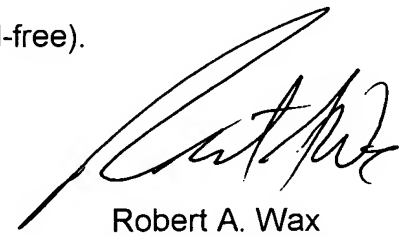
Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax
Primary Examiner
Art Unit 1653

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